

### Remarks

Claims 1-27 are pending. Applicant thanks the Examiner for allowance of Claims 23-25 for the indication that Claims 5, 7, 9-14, 16, 19, and 21 are directed to allowable subject matter.

#### I. The Amendments

Claims 1, 15, and 26 have been amended to clarify that the device and methods effect growth of the stretched blood vessel. Support for this amendment can be found throughout the specification, including page 4, lines 8-9; page 20, lines 23-27; page 32, lines 7-9; page 8, lines 1-4; page 17, lines 7-15; and page 19, lines 23-29.

New claims 28-30 have been added. Support for these claims can be found, for example, at page 31, lines 26-30; original claim 1; and page 4, lines 8-10.

#### II. Rejections Under 35 U.S.C. § 102

Claims 1-4, 6, 8, 15, 17, 18, 20, 22, 26, and 27 were rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5, 376,110 to Tu (hereinafter "Tu"). The rejection is respectfully traversed if applied to the claims as amended.

##### Applicant's Claimed Devices and Methods

Applicant has developed devices and methods for creating blood vessel grafts by axially distending a segment of an existing vessel portion, either in vivo or in vitro, to cause the vessel tissue to grow and increase the length of the blood vessel segment. The lengthened blood vessel is then suitable for use as a blood vessel graft.

##### Tu

Tu discloses an in vitro apparatus for *preserving or fixing* collagenous graft material to improve its *pliability*. (Col. 3, Lines 37-54). Tu discloses that the pliability of a collagenous

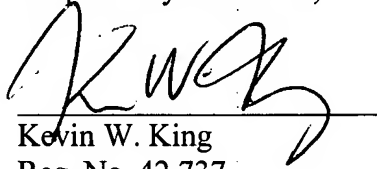
graft material (e.g., an excised segment of a blood vessel) can be maintained during a fixing process by manipulating the graft during part of the collagen cross-linking reaction. (Col. 7, lines 32-51). The graft is manipulated by compression/relaxation or stretching/relaxation, which is achieved by the movement of one end of the blood vessel with a movable clamp member. (Col. 8, lines 31-34).

Importantly, the apparatus and methods of Tu are directed to *chemically fixing or preserving* the graft material—**not to growing the tissue**. Tu fails to disclose or remotely suggest a device that is operable, or method that is effective, to axially distend a blood vessel so as to stimulate growth of the blood vessel. In particular, Tu's device and methods comprise a bath of a "fixative" solution. It is well known in the art that fixatives are commonly used to denature (render biologically inert) proteins and other molecules in living tissue by generating cross-links, i.e., by binding together molecular chains. Fixative solutions are not to be confused with tissue culture media. Fixative solutions are not used with **living** tissue because they render normally active molecules biologically inactive. Cells would die, not divide and multiply. Accordingly, Tu clearly fails to disclose, either expressly or inherently, a device or a method in which a living blood vessel is stretched in a manner effective to cause it to grow in length, as required by Applicant's claims.

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AMENDMENT AND  
RESPONSE TO OFFICE ACTION

Therefore, Applicant submits that the claims as amended are novel and nonobvious over  
Tu and the other prior art of record. Allowance of claims 1-30 is therefore earnestly solicited.

Respectfully submitted,

  
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